ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OF THE MARKETING AUTHORISATION

A MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance

Degussa AG
Plant Hanau-Wolfgang
Rodenbacher Chaussee 4
D-63457
Germany

Name and address of the manufacturer responsible for batch release

Baxter Oncology GmbH
Daimlerstraße 40
D-60314 Frankfurt
Germany

B CONDITIONS OF THE MARKETING AUTHORISATION

- **CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IMPOSED ON THE MARKETING AUTHORISATION HOLDER**

Medicinal product subject to medical prescription

- **OTHER CONDITIONS**

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

ANNEX II

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

Cetrotide 0.25 mg, powder and solvent for solution for injection.
Cetrorelix (as acetate).

- The active substance is cetrorelix acetate, 0.26 – 0.27 mg equivalent to 0.25 mg cetrorelix.
- The other ingredient is mannitol.
- The solvent is Water for Injections.

Marketing authorisation holder: Serono Europe Limited
56 Marsh Wall
London E14 9TP
United Kingdom

Manufacturer: Baxter Oncology GmbH
Daimlerstraße 40
60314 Frankfurt
Germany

1. WHAT CETROTIDE IS AND WHAT IT IS USED FOR

Cetrotide 0.25 mg is a powder for solution for injection. It is available in packs of one or seven vials.

Additionally, for each vial the packs contain

- one pre-filled syringe with solvent (water for injections) for parenteral use for dissolving the powder in the vial
- one injection needle with a yellow mark for injecting the water into the vial and withdrawing the solution from the vial
- one injection needle with a grey mark for injecting the solution
- two alcohol swabs for cleaning purposes.

Cetrotide 0.25 mg inhibits the effects of a natural hormone, called luteinising hormone releasing hormone (LHRH). LHRH regulates the secretion of another hormone, called luteinising hormone (LH), which induces ovulation during the menstrual cycle. Cetrotide 0.25 mg inhibits premature ovulation which is undesirable during hormone treatment for ovarian stimulation as only mature egg cells are suitable for fertilisation.

Therapeutic indications

Cetrotide 0.25 mg is used to prevent premature ovulation during a controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques.

In clinical trials Cetrotide 0.25 mg was used with human menopausal gonadotropin (HMG), however, limited experience with recombinant follicle stimulating hormone (FSH) suggested similar efficacy. HMG and FSH are hormones promoting egg maturation.

2. BEFORE YOU USE CETROTIDE

Do not use Cetrotide:

- if you are allergic to cetrorelix acetate, mannitol or exogenous peptide hormones (medicines similar to Cetrotide 0.25 mg).
- if you are pregnant or breast-feeding
- if you have already reached your menopause
- if you have a moderate or severe kidney or liver disease.

Take special care with Cetrotide:

Special care should be taken in women with an active allergic condition or a known history of allergy. Since treatment with Cetrotide is not advised in women with severe allergic conditions it is important that you inform your doctor of any allergies.

During or following hormonal stimulation of the ovaries an ovarian hyperstimulation syndrome can occur. This event is related to the stimulation procedure with gonadotropins (hormones promoting egg maturation). For symptoms and suitable measures please refer to the Patient Information Leaflet of the gonadotropin-containing medicine prescribed for you.

Luteal phase support (a measure to support the onset of pregnancy) should be given according to the reproductive medical centre´s practice.

There is limited experience up to now with the administration of Cetrotide 0.25 mg during a repeated ovarian stimulation procedure. Therefore you should use Cetrotide 0.25 mg in repeated cycles only after a careful risk/benefit evaluation by your doctor.

Pregnancy and breast-feeding:

You should not use Cetrotide 0.25 mg if you are already pregnant, or suspect that you might be pregnant, or if you are breast-feeding.

Driving and using machines:

As far as it is known, Cetrotide 0.25 mg does not impair your ability to drive or to operate machinery.

Using other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

Experimental investigations have shown that interactions are unlikely with medications that are metabolised in the liver. However, the possibility of interactions with commonly used medicinal products cannot entirely be excluded.

3. HOW TO USE CETROTIDE

How much Cetrotide should you use and how often should you use it?

The following statements apply to Cetrotide 0.25 mg unless otherwise prescribed by your doctor. Please observe these instructions for use, otherwise you will not fully benefit from Cetrotide 0.25 mg.

The contents of one vial (0.25 mg Cetrorelix) are to be administered once daily, at 24 h intervals, either in the morning or in the evening.

Administration in the morning: Treatment with Cetrotide 0.25 mg should begin on day 5 or 6 of ovarian stimulation (approximately 96 to 120 hours after start of ovarian stimulation) with urinary or recombinant gonadotropins and is to be continued throughout the gonadotropin treatment period including the day of ovulation induction.

Administration in the evening: Treatment with Cetrotide 0.25 mg should begin on day 5 of ovarian stimulation (approximately 96 to 108 hours after start of ovarian stimulation) with urinary or recombinant gonadotropins and is to be continued throughout the gonadotropin treatment period until the evening prior to the day of ovulation induction.

How should Cetrotide be administered?

The first injection of Cetrotide should be supervised by your doctor. You can carry out the following injections yourself as long as you have been made aware by your doctor of the symptoms that may indicate allergy, the consequences of such a reaction and the need for immediate treatment.

Cetrotide 0.25 mg is for injection under the skin of the lower abdominal wall, preferably around the navel. To minimise local irritation, please select a different injection site each day.

Dissolve Cetrotide 0.25 mg powder only with the water contained in the pre-filled syringe. Do not use a Cetrotide 0.25 mg solution if it contains particles or if it is not clear.

Before you administer Cetrotide yourself, please read the following instructions carefully:

1. Wash your hands. It is important that your hands and all items you use are as clean as possible.

2. Lay out on a clean surface everything you need (one vial, one pre-filled syringe, one injection needle with a yellow mark, one injection needle with a grey mark and two alcohol swabs).

3. Flip off the plastic cover of the vial. Wipe the aluminium ring and the rubber stopper with an alcohol swab.

4. Take the injection needle with the yellow mark and remove the wrapping. Take the pre-filled syringe and remove the cover. Put the needle on the syringe and remove the cover of the needle.

5. Push the needle through the centre of the rubber stopper of the vial. Inject the water into the vial by slowly pushing the plunger of the syringe.

6. Leave the syringe on the vial. Gently agitate the vial until the solution is clear and without residue. Avoid forming bubbles during dissolution.

7. Draw the whole contents of the vial into the syringe. If solution is left in the vial, invert the vial, pull back the needle until the opening of the needle is just inside the stopper. If you look from the side through the gap in the stopper, you can control the movement of the needle and the liquid. It is important to withdraw the entire contents of the vial.

8. Detach the syringe from the needle and lay down the syringe. Take the injection needle with the grey mark and remove its wrapping. Put the needle on the syringe and remove the cover of the needle.

9. Invert the syringe and push the plunger until all air bubbles have been expelled. Do not touch the needle or allow the needle to touch any surface.

10. Choose an injection site at the lower abdominal wall, preferably around the navel. Take the second alcohol swab and clean the skin at the injection site. Hold the syringe in one hand. Gently pinch up the skin surrounding the site of injection and hold firmly with the other hand.

11. Hold the syringe as you would hold a pencil, insert the needle completely into the skin at an angle of about 45 degree.

12. Once the needle has been inserted completely, release your grasp of the skin.

13. Pull back gently the plunger of the syringe. If blood appears continue as described in step 14. If no blood appears, inject the solution slowly by pushing the plunger gently forward. After all of the solution is injected, withdraw the needle slowly, applying gentle pressure with the alcohol swab on the skin where the needle was inserted. Withdraw the needle at the same angle as it was inserted.

14. If blood appears, withdraw the needle with the syringe and gently apply pressure to the injection site. Do not use this solution but empty the syringe in a sink. Start again with step 1.

15. Use the syringe and needles only once. Dispose of the syringe and needles immediately after use (put the covers on the needles to avoid injury).

If you use more Cetrotide than you should:

Overdosage of Cetrotide 0.25 mg may result in a prolonged duration of action but is unlikely to be associated with acute toxic effects. Therefore, in case of overdosage no specific measures are required.

If you forget to take Cetrotide:

If you forgot to take Cetrotide 0.25 mg on one day, please contact your doctor immediately and ask for advice.

Ideally Cetrotide 0.25 mg should be administered at 24 hours intervals. But if you missed to administer Cetrotide 0.25 mg at the right time it is no problem to administer this dose at a different time of the same day.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cetrotide can have side effects.

Mild and transient reactions may occur at the injection site like reddening, itching, and swelling.

Rare cases of severe generalised allergic reactions have also been reported.

Occasionally systemic side effects, like nausea and headache have been reported. In addition, a single case of pruritus has been reported during treatment with Cetrorelix.

Occasionally, stimulation of ovaries with gonadotropins (hormones promoting egg maturation) may lead to a so-called ovarian hyperstimulation syndrome (OHSS). Symptoms like abdominal pain,

tension, nausea, vomiting, diarrhoea and breathing difficulties may indicate an OHSS. Please inform your doctor immediately, if you feel such symptoms.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING CETROTIDE

Keep out of the reach and sight of children.

Do not store above 25°C.

Keep the container in the outer carton in order to protect from light.

The Cetrotide 0.25 mg powder in the vial and the solvent in the pre-filled syringe have the same expiry date. It is printed on the labels and on the carton. Do not use after the expiry date stated on the label or the carton.

The solution should be used immediately after preparation.

Do not use Cetrotide if you notice any visible signs of deterioration.

If you have any further questions please consult your doctor or pharmacist.

6. FURTHER INFORMATION

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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This leaflet was last approved on

PACKAGE LEAFLET

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

Cetrotide 3 mg, powder and solvent for solution for injection.
Cetrorelix (as acetate).

- The active substance is cetrorelix acetate, 3.12 – 3.24 mg equivalent to 3 mg cetrorelix.
- The other ingredient is mannitol.
- The solvent is Water for Injections.

Marketing authorisation holder: Serono Europe Limited
56 Marsh Wall
London E14 9TP
United Kingdom

Manufacturer: Baxter Oncology GmbH
Daimlerstraße 40
60314 Frankfurt
Germany

1. WHAT CETROTIDE IS AND WHAT IT IS USED FOR

Cetrotide 3 mg is a powder for solution for injection. It is available in a pack with one vial.

Additionally the pack contains

- one pre-filled syringe with solvent (water for injections) for parenteral use for dissolving the powder in the vial
- one injection needle with a yellow mark for injecting the water into the vial and withdrawing the solution from the vial
- one injection needle with a grey mark for injecting the solution
- two alcohol swabs for cleaning purposes.

Cetrotide 3 mg inhibits the effects of a natural hormone, called luteinising hormone releasing hormone (LHRH). LHRH regulates the secretion of another hormone, called luteinising hormone (LH), which induces ovulation during the menstrual cycle. Cetrotide 3 mg inhibits premature ovulation which is undesirable during hormone treatment for ovarian stimulation as only mature egg cells are suitable for fertilisation.

Therapeutic indications

Cetrotide 3 mg is used to prevent premature ovulation during a controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques.

In clinical trials Cetrotide 3 mg was used with human menopausal gonadotropin (HMG), however, limited experience with recombinant follicle stimulating hormone (FSH) suggested similar efficacy. HMG and FSH are hormones promoting egg maturation.

2. BEFORE YOU USE CETROTIDE

Do not use Cetrotide:

- if you are allergic to cetrorelix acetate, mannitol or exogenous peptide hormones (medicines similar to Cetrotide 3 mg).
- if you are pregnant or breast-feeding
- if you have already reached your menopause
- if you have a moderate or severe kidney or liver disease.

Take special care with Cetrotide:

Special care should be taken in women with an active allergic condition or a known history of allergy. Since treatment with Cetrotide is not advised in women with severe allergic conditions it is important that you inform your doctor of any allergies.

During or following hormonal stimulation of the ovaries an ovarian hyperstimulation syndrome can occur. This event is related to the stimulation procedure with gonadotropins (hormones promoting egg maturation). For symptoms and suitable measures please refer to the Patient Information Leaflet of the gonadotropin-containing medicine prescribed for you.

Luteal phase support (a measure to support the onset of pregnancy) should be given according to the reproductive medical centre´s practice.

There is limited experience up to now with the administration of Cetrotide 3 mg during a repeated ovarian stimulation procedure. Therefore you should use Cetrotide 3 mg in repeated cycles only after a careful risk/benefit evaluation by your doctor.

Pregnancy and breast-feeding:

You should not use Cetrotide 3 mg if you are already pregnant, or suspect that you might be pregnant, or if you are breast-feeding.

Driving and using machines:

As far as it is known, Cetrotide 3 mg does not impair your ability to drive or to operate machinery.

Using other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

Experimental investigations have shown that interactions are unlikely with medications that are metabolised in the liver. However, the possibility of interactions with commonly used medicinal products cannot entirely be excluded.

3. HOW TO USE CETROTIDE

How much Cetrotide should you use and how often should you use it?

The following statements apply to Cetrotide 3 mg unless otherwise prescribed by your doctor. Please observe these instructions for use, otherwise you will not fully benefit from Cetrotide 3 mg.

The contents of 1 vial (3 mg cetrorelix) are to be administered on day 7 of ovarian stimulation (approximately 132 to 144 hours after start of ovarian stimulation) with urinary or recombinant gonadotropins.

A single dose of Cetrotide 3 mg results in a duration of action of at least 4 days. If the follicle growth does not allow ovulation induction on the fifth day after injection of Cetrotide 3 mg, additionally 0.25 mg cetrorelix (Cetrotide 0.25 mg) should be administered once daily beginning 96 hours after the injection of Cetrotide 3 mg until the day of ovulation induction.

How should Cetrotide be administered?

The first injection of Cetrotide should be supervised by your doctor. You can carry out the following injections yourself as long as you have been made aware by your doctor of the symptoms that may indicate allergy, the consequences of such a reaction and the need for immediate treatment.

Cetrotide 3 mg is for injection under the skin of the lower abdominal wall, preferably around the navel.

Dissolve Cetrotide 3 mg powder only with the water contained in the pre-filled syringe. Do not use a Cetrotide 3 mg solution if it contains particles or if it is not clear.

Before you administer Cetrotide yourself, please read the following instructions carefully:

1. Wash your hands. It is important that your hands and all items you use are as clean as possible.

2. Lay out on a clean surface everything you need (one vial, one pre-filled syringe, one injection needle with a yellow mark, one injection needle with a grey mark and two alcohol swabs).

3. Flip off the plastic cover of the vial. Wipe the aluminium ring and the rubber stopper with an alcohol swab.

4. Take the injection needle with the yellow mark and remove the wrapping. Take the pre-filled syringe and remove the cover. Put the needle on the syringe and remove the cover of the needle.

5. Push the needle through the centre of the rubber stopper of the vial. Inject the water into the vial by slowly pushing the plunger of the syringe.

6. Leave the syringe on the vial. Gently agitate the vial until the solution is clear and without residue. Avoid forming bubbles during dissolution.

7. Draw the whole contents of the vial into the syringe. If solution is left in the vial, invert the vial, pull back the needle until the opening of the needle is just inside the stopper. If you look from the side through the gap in the stopper, you can control the movement of the needle and the liquid. It is important to withdraw the entire contents of the vial.

8. Detach the syringe from the needle and lay down the syringe. Take the injection needle with the grey mark and remove its wrapping. Put the needle on the syringe and remove the cover of the needle.

9. Invert the syringe and push the plunger until all air bubbles have been expelled. Do not touch the needle or allow the needle to touch any surface.

10. Choose an injection site at the lower abdominal wall, preferably around the navel. Take the second alcohol swab and clean the skin at the injection site. Hold the syringe in one hand. Gently pinch up the skin surrounding the site of injection and hold firmly with the other hand.

11. Hold the syringe as you would hold a pencil, insert the needle completely into the skin at an angle of about 45 degree.

12. Once the needle has been inserted completely, release your grasp of the skin.

13. Pull back gently the plunger of the syringe. If blood appears continue as described in step 14. If no blood appears, inject the solution slowly by pushing the plunger gently forward. After all of the solution is injected, withdraw the needle slowly, applying gentle pressure with the alcohol swab on the skin where the needle was inserted. Withdraw the needle at the same angle as it was inserted.

14. If blood appears, withdraw the needle with the syringe and gently apply pressure to the injection site. Do not use this solution but empty the syringe in a sink.

15. Use the syringe and needles only once. Dispose of the syringe and needles immediately after use (put the covers on the needles to avoid injury).

If you use more Cetrotide than you should:

Overdosage of Cetrotide 3 mg may result in a prolonged duration of action but is unlikely to be associated with acute toxic effects. Therefore, in case of overdosage no specific measures are required.

If you forget to take Cetrotide:

If you forgot to take Cetrotide 3 mg, please contact your doctor immediately and ask for advice.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cetrotide can have side effects.

Mild and transient reactions may occur at the injection site like reddening, itching, and swelling.

Rare cases of severe generalised allergic reactions have also been reported.

Occasionally systemic side effects, like nausea and headache have been reported. In addition, a single case of pruritus has been reported during treatment with Cetrorelix.

Occasionally, stimulation of ovaries with gonadotropins (hormones promoting egg maturation) may lead to a so-called ovarian hyperstimulation syndrome (OHSS). Symptoms like abdominal pain, tension, nausea, vomiting, diarrhoea and breathing difficulties may indicate an OHSS. Please inform your doctor immediately, if you feel such symptoms.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING CETROTIDE

Keep out of the reach and sight of children.

Do not store above 25°C.

Keep the container in the outer carton in order to protect from light.

The Cetrotide 3 mg powder in the vial and the solvent in the pre-filled syringe have the same expiry date. It is printed on the labels and on the carton. Do not use after the expiry date stated on the label or the carton.

The solution should be used immediately after preparation.

Do not use Cetrotide if you notice any visible signs of deterioration.

If you have any further questions please consult your doctor or pharmacist.

6. FURTHER INFORMATION

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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